

Remarks

Claims 1-24 were pending in the subject application. By this Amendment, Applicants have canceled claims 1-24 and rewritten the elected group of claims as new claims 25-39 in order to replace references to "IFN" with the term "interferon." In addition, the specification has been amended to correct minor typographical errors therein. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 25-39 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants believe that the pending claims are in condition for allowance. Such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Marked-Up Version of Substituted Paragraphs



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Docket No. UF-243X
Serial No. 09/648,864

Marked-Up Version of Substituted Paragraphs

Paragraph on page 1, line 19:

IFN α 's have been shown to inhibit various types of cellular proliferation. IFN α 's are especially useful against hematologic malignancies such as hairy-cell leukemia (Quesada *et al.*, 1984). Further, these proteins have also shown activity against multiple myeloma, chronic lymphocytic leukemia, low-grade lymphoma, Kaposi's sarcoma, chronic myelogenous leukemia, renal-cell carcinoma, urinary bladder tumors and ovarian cancers (Bonnem *et al.*, 1984; Oldham, 1985). The role of interferons and interferon receptors in the pathogenesis of certain autoimmune and inflammatory diseases has also been investigated (Benoit *et al.*, 1993).

Paragraph on page 2, line 12:

Interferon-tau (IFN τ) is a member of the type I IFN family but, unlike IFN α and IFN β , IFN τ lacks toxicity at high concentrations *in vitro* and when used *in vivo* in animal studies (Bazer *et al.*, 1989; Pontzer *et al.*, 1991; Soos, Johnson, 1995; Soos, *et al.*, 1995; Soos *et al.*, 1997; Khan *et al.*, 1998). IFN τ was originally identified as a pregnancy recognition hormone produced by trophoblasts cells of the placenta of ruminants such as sheep and cows (Bazer *et al.*, 1991; Godkin *et al.*, 1982; Imakawa *et al.*, 1987; Johnson *et al.*, 1994). It has been reported that a human IFN τ exists (Whaley *et al.*, 1994) but this observation has not been confirmed. Thus, it is currently unknown as to whether there is a human IFN τ . IFN τ exhibits antiviral and cell inhibitory properties which are very similar to that of IFN α and IFN β (Bazer *et al.*, 1989; Pontzer *et al.*, 1991; Soos, Johnson, 1995). However, IFN τ lacks the cellular toxicity associated with high concentrations of IFN α and IFN β (Bazer *et al.*, 1989; Pontzer *et al.*, 1991). Further, the weight loss and bone marrow suppression that is associated with administering high doses of IFN α and IFN β to individuals is absent with IFN τ in animal systems (Soos, Johnson, 1995; Soos *et al.*, 1995; Soos *et al.*, 1997). Studies have shown that the N-terminus of type I IFNs play a role in the toxicity or lack thereof for an IFN (Pontzer *et al.*, 1994; Subramaniam *et al.*, 1995).



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Paragraph on page 19, line 15:

Benoit, P., D. Maguire, I. Plavec, H. Kocher, M. Tovey, F. Meyer (1993) "A monoclonal antibody to recombinant human IFN-alpha receptor inhibits [biologic] biological activity of several species of human IFN-alpha, IFN-beta, and IFN-omega. Detection of heterogeneity of the cellular type I IFN receptor" *J. Immunol.* 150(3):707-716.

Paragraph on page 20, line 17:

Hamelmann, E., A. Oshiba, J. Paluh, K. Bradley, J. Loader, T.A. Potter *et al.* (1996) "Requirement for CD8⁺ T cells in the development of airway hyperresponsiveness in a murine model of airway sensitization" *J. Exp. Med.* [186:1719-29] 183:1719-29.

Paragraph on page 22, line 1:

Oldham, R.K. (1985) "Biologicals for cancer treatment: interferons" *Hospital Practice* [20(12):71-74] 20(12):71-91.

Paragraph on page 22, line 10:

Quesada, J.R., J. Reuben, J.T. Manning, E.M. Hersh, J.U. Gutterman (1984) "Alpha Interferon for Induction of Remission in Hairy-Cell Leukemia" *New England Journal of Medicine* [310:15] 310:15-18.